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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,364	09/06/2000	Alice C. Martino	6107.N CN2	3730

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/656,364	MARTINO ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-20,22-24,26,34,36-38 and 68-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-20,22-24,26,34,36-38 and 68-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment filed on August 20, 2004 has been entered. Claims 2-20, 22-24, 26, 34, 36-38, 68-70 are pending. Any rejection previously on record that is not addressed in this Office Action is considered obviated in view of the amendments.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-20, 22-24, 26, 34, 36-38, 68-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makooi-Morehead US Patent 6,238,695 in view of Elger US Patent 4,844,907 (Elger).

Applicant's arguments with respect to this rejection have been fully considered but are not persuasive. Applicant first argues that there is no motivation to combine the teachings of Makooi-Morehead with the teachings of Elger. Applicant argues that the inventors of the cited patents are trying to solve different problems. (See Arguments at page 18)b.

In response Examiner states that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Here, the modifications of Makooi-Morehead are merely based on substituting the active drug recited in Elger. Such modifications are based on what the state of art of pharmaceutical formulation is and what is construed from the teachings of Makooi-Morhead and Elger

by one of ordinary skill in the art. Examiner has taken the position that the modifications described flow naturally from the suggestions of the prior art as all elements of the instant claims are described by the cited references. Applicant has not provided any evidence showing otherwise. Thus, the rejection is maintained.

Applicant also argues that the cited prior arts are not combinable because the compositions of Makooi-Morehead requires lubricant in small amounts and the compositions of Eldger does not require a lubricant. Applicant further adds that Eldger is directed to the use of a self-lubricating compression aid. (see Arguments at pages 19-21).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, the rejection is based on the combined teachings that the cited references provide to one of ordinary skill in the art. Accordingly, the rejection is based on their combined teachings and what would have suggested to one of ordinary skill in the art of pharmaceutical formulation. Since, the combined teachings of Makooi-Morehead and Elger meet all the limitations of the instant claims. The rejection is deemed to be proper.

Further, Applicant appears to be mischaracterizing the teachings of Makooi-Morehead and Elger as two sets of teachings that are directed away from each other. (see Arguments at page 19). However, Examiner would like to address that the

teachings of Makooi-Morehead are not a direct teaching away from those described by Elger. Thus, Applicant's conclusion that they are not combinable is not correct.

Here, Applicant appears to misinterpret what it means to "teach away" from a patented invention. Generally, "disclosed examples and preferred embodiments do not constitute a teaching which is away from a broader disclosure or nonpreferred embodiments." *In re Susi*, 169 USPQ 423 (CCPA 1971). "In general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the results sought by the applicant." *In re Gurley,* 31 USPQ2d 1130, 1131-2 (Fed. Cir. 1994). In the instant case, the mere fact that Elger offers an alternative way of providing the lubricant properties in his composition does not preclude modifications of Makooi-Morehead's formulations that may be obvious over the teachings of Elger.

Specifically, the portions of Elger's patent that Applicant characterizes as a "teaching away" from the use of lubricants (col 5, lines 8-22) does not discourage one of ordinary skill in the art to employ a lubricant as instantly claimed in Makooi-Morehead types formulations. In fact, Elger advocates the need for the use of a lubricant during the process of making tablets. (col 3, lines 44-50). Elger clearly state that his formulation employs such concentrations of compression aids to provide the lubricating effects provided by conventional lubricants. (see col 4, line 61-col 5, line 7). One of ordinary skill in the art would have been able to determine how much or when to use compounds providing lubricant properties to create a tablet with optimal characteristics.

Therefore, the teaching of Elger is not viewed to be an absolute bar for using any lubricant in a tablet formulation.

Second, the rejection of record merely uses Elger to show that for purposes of preparing a tablet, the salt forms of rapidly precipitating drugs that fall within the scope of instant claims are essentially functional equivalents to their free base or free acids forms. Note for example the recitation of narcotic analgesics such as hydromorphone or its hydrochloride salts as preferred form. (col 2, lines 4-15).

third, there is no statement in Elger showing that the instantly claimed formulations would have been a less attractive composition for drug delivery. Therefore, Examiner concludes that one ordinary skill, upon reading the Elger's reference, would not have been discouraged from using salts forms of compounds in the path set out by Makooi-Morehead, or would have taken a direction divergent from the path that was taken by the applicant.

Finally, Applicant's assertion that Makooi-Morehead does not use a fairly soluble or highly soluble salt of poorly soluble free acid or free base is not accurate. Makooi-Morehead clearly provides for formulations that comprise all suitable type of Efavirnez compounds for pharmaceutical use including its salts forms. Note that at col 3, lines 5-10, Makooi-Morehead incorporates all the teachings and possible variations of Efavirenz from US Patent 5,519,021 (US '021). The teachings in US '021 is also directed to all suitable salts of Efavirnez. (see US '021 at abstract, examples 1-8, claims 1-10). Therefore, Applicant's arguments that Makooi-Morehead discourages the use of

Efavirnez salts or that Makooi-Morehead only uses poorly soluble free acid or free base form of Efavirnez is not correct.

Makooi-Morehead shows all elements of the instant claims except the exact drugs recited in claim 70. Moakooi-Morehead uses Efavirnez with lactose; a flow agent, such as colloidal silicon dioxide; a superdisintegrants, such as croscarmellose and sodium glycolate, and a binder, such as microcrystalline. Makooi teaches that such combination of ingredients improves the rate of dissolution and thus the extent of absorption in the GI-track. (col 2, lines 3-7). Accordingly utilizing them and further optimizing their concentrations for desired rate and extent of absorption is well within purview of an ordinary artisan (see col 5, line 40-col 6, line16; col 7, line15-col 8, line33).

Elger's teachings are discussed extensively on the record. Elger provides for various types of drugs within the scope of the instant claim 38 that are highly insoluble in water. Such drugs include hydromorphone, hydrocodeine, and salts thereof (see entire col 2).

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute Makooi-Morehead's drug with other suitable insoluble agents as recited in Elger, because as taught by Makooi-Morehead, the ordinary artisan would have had a reasonable expectation of success in improving the rate of dissolution of a insoluble drug and subsequently its extent of absorption in GI track.

Conclusion

No claims are allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER